REMARKS

Status of the claims

Claims 1-38 are pending and claims 1-15 and 17-37 are under consideration in this application, claims 16 and 38 having been withdrawn for allegedly being drawn to a separate invention. Claim 16 is allowable.

For the record, as indicated above, the Office Action indicates on page 2 that claim 16 was withdrawn from further consideration. On the other hand, on page 16, it is indicated to be in condition for allowance. As claim 16 has been cancelled (see below), the issue is moot. In addition, in paragraph 4 of the Office Action Summary, it is stated that claims 1-37 are pending. While, as indicated above, claim 38 has been withdrawn from further consideration (see page 2 of the Office Action), it has not been cancelled. It is thus still "pending" in this application. Nevertheless, as claim 38 is cancelled herein, the issue is moot.

Claims 16-38 are cancelled.

After entry of the amendments made herein, claims 1-15 will be pending and under consideration in this application.

Information Disclosure Statement (IDS)

With respect to the comments on page 2, line 11, to page 3, line 7, of the Office Action, the Examiner left Applicants' undersigned representative a voice mail message on Thursday. July 17, 2008, indicating that the IDS filed on October 4, 2006, was in good order and that all the references had been considered. Applicants note however that in the copy of the PTO-1449 form (submitted by Applicants with that IDS) that was enclosed with the instant Office Action, the citations of references AH, AJ, AK, AM, AN, AO, AQ, and AR were not initialed by the Examiner. Applicants respectfully request that another copy of the PTO-1449 form with these citations initialed by the Examiner be mailed to Applicants' undersigned representative.

Claim objections

Claims 10-15 and 17 are objected to.

Claim 17 is cancelled.

Claims 10-15 are objected to for being dependent on rejected claims. For the reasons given below, claims 1-9 are neither anticipated by, nor obvious in view of, the cited art. Therefore, Applicants respectfully request that the objection to claims 10-15 be withdrawn.

35 U.S.C. § 112, second paragraph, rejections

Claims 18-37 stand rejected on the grounds that there is allegedly insufficient antecedent basis for the limitation "fistula" in the claims. The rejection is moot in view of the cancellation of these claims.

35 U.S.C. § 103(a) rejection

Claims 1-3, 5, 6, and 9 stand rejected on the grounds that they are allegedly unpatentable over Hansbrough et al. Applicants respectfully traverse the rejection.

From the comments on page 4, lines 15-23, of the Office Action, Applicants understand the Examiner's position to be that, in disclosing placement of composites containing cultured autologous keratinocytes and fibroblasts, Harnsbrough et al. renders the present claims obvious. Applicants respectfully disagree with this position.

First, Applicants submit that placing a sheet of cells alone onto a wound is a very different proposition from injecting a suspension of cells into a wound. A sheet of cells resembles more closely natural skin than does a suspension of cells in which there are few if any physical links between individual cells in the suspension. While such a sheet of cells would be expected to stay in place on the wound, injected cells would be free to migrate out of the wound and into the subject's body and, possibly, circulatory system. However, the composites used by Harnsbrough et al. were even more different from the injectable cell suspensions of the instant claims than sheets of cells. In these composites, the keratinocytes and fibroblasts were attached to matrix membranes composed of collagen and glycosaminoglycan and the resulting composite were placed on the wounds (see, e.g., page 2125, column 3, second full paragraph, to page 2125, column 2, first full paragraph). The clear advantage of these biological membrane bound cell

composites over either keratinocyte cell suspensions or keratinocyte sheets is indicated by the reference at, for example, page 2128 to page 2129, paragraph spanning column 1 and 2. Notably, no mention is made of fibroblast suspensions or sheets of fibroblasts without a membrane in the reference.

Certainly, from his own knowledge and without additional information, one of ordinary skill in the art would not consider it obvious to modify the teachings of Harnsbrough et al. and hence to inject a suspension of fibroblasts into a wound of an animal such as a human patient. Moreover, in the unlikely event that such an artisan did attempt to do it, in view of the lack of teachings in the art in this respect, he or she would have had no reasonable expectation of success.

In light of the above considerations, Applicants respectfully submit that the claims listed above are not obvious in view of the Harnsbrough reference and respectfully request the rejection under 35 U.S.C. § 103(a) be withdrawn.

35 U.S.C. § 102(b) rejection

Claims 1-9 stand rejected as allegedly being anticipated by DE197 16 098 (DE'098). Applicants respectfully traverse the rejection.

From the comments on page 5, lines 81-13, of the Office Action, Applicants understand the Examiner's position to be that the DE'098 discloses all the limitations of claim 1. Applicants respectfully disagree with this position.

The Office Action refers to, *inter alia*, page 4, column 17, of DE'098. Applicants can find no column 17 on page 4 in DE'098.

DE'098 deals with gene therapy. As indicated in the English language translation of the DE'098 abstract (submitted with Information Disclosure Statement filed on October 4, 2006), page 2, lines 22-25, and claims 1 and 12 of DE'098, the reference requires that the fibroblasts used in its compositions contain at least one foreign gene coding for a cytokine that promotes wound healing and at least another component that promotes wound healing. There is no disclosure or the least suggestion in the instant application that fibroblasts used in the claimed

methods contain any foreign gene, let alone one coding for a cytokine that promotes wound healing. Indeed, as indicated, for example, on page 5, lines 15-17, of the instant specification, "obtaining autologous fibroblasts" (the first step in claim 1) means obtaining fibroblasts "from an animal, such as a mammal, particularly a human." There is no suggestion that such an animal have in its cells a gene coding for a cytokine that promotes wound healing.

Moreover, while Applicants and Applicants' undersigned representative are not fluent in German, they are not aware of disclosure in the text of DE'098 cited in the Office Action of step (b) of claim 1, i.e., "culturing the fibroblasts in a culture medium such that the cultured fibroblasts are non-immunogenic when administered", and in particular, disclosure of culturing the fibroblasts in the subject's own serum as asserted in the Office Action.

In light of the above considerations, Applicants submit that instant claims are not anticipated by DE'098 and therefore respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

In summary, in view of the amendments and remarks set forth above, Applicants request that the Examiner permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number below.

Applicants submit herewith a request for an automatic extension of time. Please apply the charges for the extension of time and any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 10592-023US1.

Respectfully submitted,

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